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NIH and FDA Announce Collaborative Initiative to Fast-track Innovations to the Public

Partnership Combines Strengths to Speed New Treatments to Patients

The U.S. Food and Drug Administration and the National Institutes of Health today unveiled an initiative designed to accelerate the process from scientific breakthrough to the availability of new, innovative medical therapies for patients.

The initiative involves two interrelated scientific disciplines: translational science, the shaping of basic scientific discoveries into treatments; and regulatory science, the development and use of new tools, standards and approaches to more efficiently develop products and to more effectively evaluate product safety, efficacy and quality. Both disciplines are needed to turn biomedical discoveries into products that benefit people.

As part of the effort, the agencies will establish a Joint NIH-FDA Leadership Council to spearhead collaborative work on important public health issues. The Joint Leadership Council will work together to help ensure that regulatory considerations form an integral component of biomedical research planning, and that the latest science is integrated into the regulatory review process.

In addition, the NIH and the FDA will jointly issue a Request for Applications, making \$6.75 million dollars available over three years for work in regulatory science. The research supported through this initiative should add to the scientific knowledge base

by providing new methods, models or technologies that will inform the scientific and regulatory community about better approaches to evaluating safety and efficacy in medical product development.

"We've all been following the remarkable advances in biomedical sciences led by the NIH with great enthusiasm for years," said HHS Secretary Kathleen Sebelius. "However, much more can be done to speed the progress from new scientific discoveries to treatments for patients. Collaboration between NIH and FDA, including support for regulatory science, will go a long way to foster access to the safest and most effective therapies for the American people."

The effort will rely on the NIH's vast experience supporting and facilitating new discoveries in the laboratory and clinic, and the FDA's more than 100 years of experience and knowledge in the regulation and approval of drugs, biologics and medical devices.

"The FDA plays an essential and unique role in how therapies are evaluated. We are the bridge between biomedical research discoveries and new medical products," said Margaret A. Hamburg, M.D., Commissioner of Food and Drugs. "We now have a special opportunity—and responsibility—to harness advances in science and technology to support our efforts. We are working in collaboration with the best minds and research institutions available, so that we can better develop and utilize new tools, standards and approaches needed to properly assess the safety, effectiveness and quality of products currently in development or already on the market."

"For more than two decades, the NIH and the FDA have been partners in many initiatives designed to improve the health of millions of Americans," said NIH Director Francis S. Collins, M.D., Ph.D. "This collaboration, however, is the first of its kind and will use the NIH's breadth of experience as a leader in biomedical sciences to help make the translation of biomedical discoveries into effective treatments as seamless as possible."

The FDA and the NIH will hold a public meeting in the spring to solicit input on how the agencies can work better together.

For more information:

Regulatory Science at FDA

<http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/default.htm>

About FDA

<http://www.fda.gov/>

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